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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,673	09/28/2001	Daniel Redoules	PF 103 PCT US	3831

25666 7590 10/21/2003

THE FIRM OF HUESCHEN AND SAGE
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350 EAST MICHIGAN AVENUE
KALAMAZOO, MI 49007

EXAMINER

KHARE, DEVESH

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 10/21/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,673

Applicant(s)

REDOULES ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-22 and 24-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 16-22 and 24-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

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Applicant's Amendment and remarks filed on 07/07/03 are acknowledged.

Claims 16,18,20,21,24, and 26 have been amended. New claims 31-33 have been added. Claim 23 has been cancelled. Claims 16-22 and 24-33 are currently pending in this application. The rejection of claims 16,18,20,24 and 26 under 35 U.S.C. 112, second paragraph, has been overcome through applicants' amendment to the claims.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bollag et al. (U.S. Patent 4,565,863) in view of von Deessen et al. (U.S. Patent 5,126,500) of record.

The claims 16-30 are directed to glucosyl complex of retinoic acid, which are broadly comprised of two components:

- (1) a glucosyl complex of retinoic acid, where glucose is attached to a linear, branched or cyclized hydrocarbon based spacer group of aliphatic or aromatic nature and a retinoic acid molecule is linked to the spacer via a carboxylate function and its pharmaceutical composition for percutaneous application; and
- (2) a process for preparing the said complex wherein the a compound of formula II (glucosyl intermediate) is reacted with retinoyl chloride. Additional claim limitations claimed include the identity of the active principle, the identity of specific characteristics

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of the E variable, specific glucosyl complexes, pharmaceutical & cosmetic compositions, % by weight of glucosyl complex composition formulations, and process for preparing compounds of claim 16.

Bollag et al. teach retinoids complex where a residue of sugar is attached via an ester to a retinoic acid derivative, its composition for topical use and a process for preparing the sugar complex of retinoic acid using the retinoic chloride intermediate(see abstract). On column 1, lines 54-57, the lower alkyl glucoside complexes of retinoic acid derivatives are disclosed. On column 3, lines 49-52, the topical administration of the pharmaceutical compositions of these complexes is taught. On column 4, Example 1, retinoic acid chloride intermediate is reacted with a glucoside to form a reaction product of a glucosyl complex of retinoic acid derivative. It would have been obvious to use the retinoyl chloride to react with formula II (a and b) to prepare the compound of formula II in claims 27-30. While the Bollag et al. retinoids complex and a process for their preparation are closely analogous to the applicant's process, Bollag et al's. glucosyl - retinoid complex and compositions differ from applicant's glucosyl -retinoid complex and compositions in that the retinoic acid is substituted with methoxy and methyl groups and the retinoic acid derivative is directly linked to the glucosyl group without a spacer group in between.

Applicants claim the glucosyl complex according to claim 21, wherein E represents 1,2-propenyl, daidzin or genistin groups. It would have been obvious to modify the compounds of formula I in col. 1, lines 5-15 of the Bollag et al. patent by substituting the

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lower alkyl groups with 1,2-propanyl, daidzin or genistin groups as taught by Bollag et al.

Applicants claim the glucosyl-retinoid complex composition for topical use according to claim 24, which contains from 0.001% to 10% by weight of glucosyl complex, see col. 3, lines 59-62 of the Bollag et al. patent wherein about 0.05 to about 5% of glucoside complex of retinoic acid derivatives is used in salves or creams.

von Deessen et al. teach the retinyl glycosides and a method of preparation of retinyl glycosides and intermediates. von Deessen et al. teach a method of preparation of retinyl β -D-glucopyranoside in Example 1 on column 7. It is noted that von Deessen et al. does not provide specific disclosures regarding the use of a carboxylate function in the linkage between a glucosyl group and a retinoic acid.

Therefore, one of ordinary skill in the art would have found the applicants claimed a glucosyl complex of retinoic acid, its pharmaceutical composition and a process for their preparation to have been obvious at the time the invention was made having the above cited references before him. Since Bollag et al. teach retinoids complex where a residue of sugar is attached via a ester to a retinoic acid derivative, the method of preparation of the complex by using the retinoic acid chloride intermediate and the topical use of its pharmaceutical composition and von Deessen et al., teach the retinyl glycosides and a method of preparation of retinyl β -D-glucopyranoside by the glycosidation reaction of a glucopyranosyl unit and retinoic acid, one skilled in the art would have a reasonable expectation for success in combining both references to accomplish the glucosyl complex of retinoic acid, its pharmaceutical composition and a process for their

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preparation. The motivation for doing so is provided by Bollag et al., which suggests the use of retinoids where a sugar is linked ester-wise to a retinoic acid derivative can be used as medicaments (Column 1, summary of invention).

Rejection Maintained

Rejection of claims 16-22 and 24-30 under 35 U.S.C. 103(a) is maintained. New claims 31-33 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Bollag et al. (U.S. Patent 4,565,863) in view of von Deessen et al. (U.S. Patent 5,126,500), as already applied to claims 16-22 and 24-30.

Claim 31 is dependent on the amended claim 20, specifying the compounds of claim 20.

Claim 32 is dependent on the amended claim 24, specifying the preferred range of claim 24. Claim 33 is dependent on claim 26, specifying the limitations of claim 26.

Claims 31-33 are obvious within the prior art already set forth in the rejections of claims 16-22 and 24-30.

Response to Arguments

Applicant's arguments filed on July 7, 2003 traversing the rejection of claims 1-22 and 24-30 under 35 U.S.C 103(a) have been fully considered but they are not persuasive.

Regarding Bollag reference, applicants present the argument that "Bollag does not disclose 'spacer' heterocyclic groups".

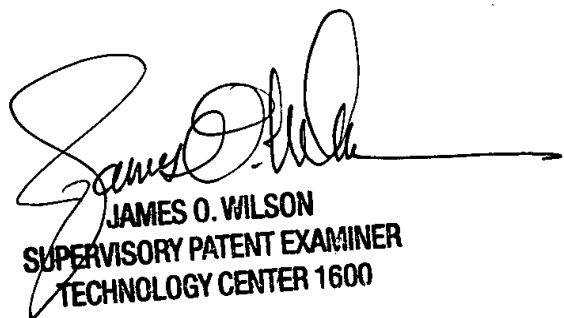
Applicant has not demonstrated any criticality or unexpected result, which stems from selection of a 'spacer' heterocyclic group between the retinoic acid derivative and the glucosyl group. Bollag et al. teach retinoids complex where a residue of sugar is

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attached via an ester to a retinoic acid derivative and von Deessen et al., teach the retinyl glycosides, therefore the use of retinoids where a sugar is linked ester-wise to a retinoic acid derivative as medicaments and the process of making these compounds are within the teachings of Bollag and von Deessen. Regarding von Deessen reference, applicants are referred to col. 7, lines 15-40, wherein the preparation of the neopentylglycoacetal glycoside of glucose (heterocyclic glycoside of glucose) is disclosed. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
October 17,2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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